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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,532	02/11/2002	Brian Connell	DI-5774	6676

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EXAMINER

MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/074,532	Applicant(s) CONNELL ET AL.	
	Examiner Manuel Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/12/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 18-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/25/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

The examiner wants to thank applicant for pointing out that Groups I and II are switched. Additionally, applicant's election with traverse of **claims 12-17** in the reply filed on December 12, 2005 is acknowledged. The traversal concerns the finding that each of Groups I to IV is separately useable. Applicant alleges that the above conclusion is not necessarily the case because the cap of claim 1 is usable with the connector of claim 12 and the method of claim 18 is useable with the method of claim 27.

In response to the comments concerning claims 1 and 12, the requirement is, *inter alia*, that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). Accordingly, the cap is disclosed so broadly, that it can be used with other combinations, and therefore, it would not be unreasonable to maintain the restriction requirement.

In response to the comments concerning claims 18 and 27, the MPEP requires a showing that the inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The method of claim 27 specifically discloses one line connected to a container and another line connected to a cavity in a patient. The preamble of claim 27 clearly states "a method for providing peritoneal dialysis". On the other hand, the method in claim 18 is only concern with providing a connection of two lines whose sources and destinations are not disclosed in the claim. Accordingly,

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based on the structural differences mentioned above, both methods have different modes of operation, different functions, or different effects. Therefore, it would not be unreasonable to maintain the restriction requirement.

Claims 1-11 and 18-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 12, 2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

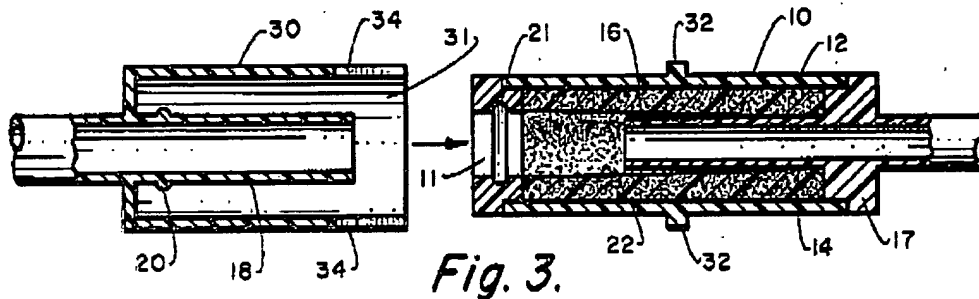
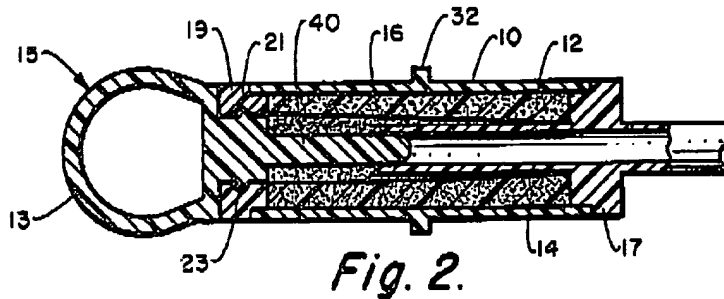
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

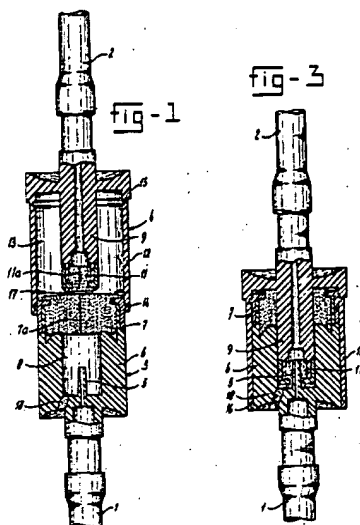
Claims 12 is rejected under 35 U.S.C. 102(b) as being anticipated by **Rogers**.



In figures 2 and 3, the Rogers patent shows a cap (10) defining a fluid flow passage (11), an amount of a disinfectant (12) sealed within the cap (10), and a shell (30) movably engaging the cap and including a fluid communication member (18), wherein the fluid communication member (18) is capable of piercing a sealed end (22) of the cap (10) and fluidly communicating with the fluid flow passage (11) when the shell (30) is moved with respect to the cap (10).

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Claims 12, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by **Wolff-Mooij**.



In figures 1 and 3, the **Wolff-Mooij** patent shows a cap (3) defining a fluid flow passage (8), an amount of a disinfectant¹ sealed within the cap (3), and a shell (4) movably engaging the cap and including a fluid communication member (9), wherein the fluid communication member (9) is capable of piercing a sealed end (7) of the cap (3) and fluidly communicating with the fluid flow passage (8) when the shell (4) is moved with respect to the cap (3).

In relation to **claim 16**, sealed end (7) includes a slit septum (7a).

In relation to **claim 17**, since sealed end (7) is sprayed with disinfectant, said sealed end (7) seals an amount of disinfectant about the fluid flow passage (8).

¹ In column 4, lines 53-57, the specification states that barriers 7 and 11, and space 13 are sprayed with a disinfectant. Accordingly, since barrier (7) is located within the extreme end of cap (3), some disinfectant has to be sealed within the cap (3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Rogers or Wolff-Mooij in view of Bellotti, et al., or Genatempo, et al.**

Rogers and Wolff-Mooij do not disclose the use of povidone iodine as the disinfectant utilized in their connectors. However, the use of povidone iodine in medical connectors is conventional in the art as evidenced by the teachings of Bellotti, et al., or Genatempo, et al.

Bellotti, et al., discloses in column 4, lines 50 and 51, the use of povidone iodine on porous pad (56). Alternatively, Genatempo, et al., also demonstrates in column 3, lines 4-6, the conventionality of using povidone iodine as disinfectant in medical connectors.

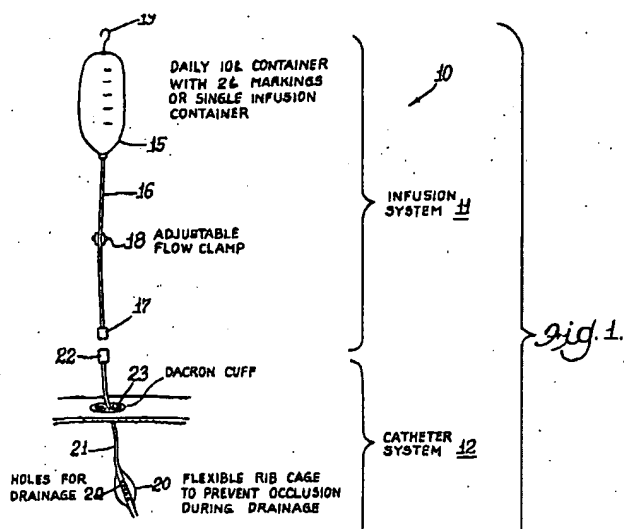
Based on the above observations, for a person of ordinary skill in the art, modifying the disinfectant used in the apparatuses disclosed by **Rogers or Wolff-Mooij** with povidone iodine would have been considered obvious in view of the proven conventionality of this enhancement. Importantly, the use of povidone iodine would have augmented the efficiency of the medical apparatus since loss of the disinfectant by evaporation would have been greatly reduced.

Claims 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Rogers in view of Genatempo, et al., or Barrington**. The Rogers patent does not disclose a tip protector that abuts an end of the shell that opposes the sealed end of the cap. The tip protector disclosed by Rogers is located in the female side of the connector. However, the use of tip connectors in the male side of a connector is well known in the art as evidenced by Genatempo, et al., or Barrington.

Genatempo, et al., shows in figures 1-3 a tip protector for the male side of the connector. On the other hand, Barrington shows in figure 1, the use of a tip protector (30) in the female side of the connector. Based on the above observations, modifying the connector disclosed by Rogers with a tip protector for the male side of the connector would have been considered obvious in view of the proven conventionality of this enhancement. Additionally, using tip protectors for the male and female sides of a connector would have enhanced the safety standards of the apparatus.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Rogers in view of Popovich, et al.** The Rogers patent does not disclose the intended uses of the lines that are attached by the connector. However, the use of a connector to attach lines running to a dialysate container and to a catheter inserted in a body is conventional in the art as evidenced by the teachings of Popovich, et al.

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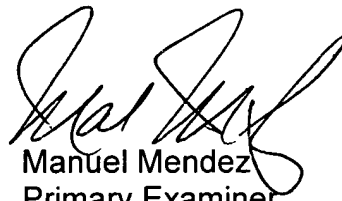
In figure 1, Popovich, et al., shows a connector that attaches lines running to a dialysate container and to a catheter inserted in a body. Accordingly, modifying the connector disclosed by Rogers with the intended uses disclosed above, as taught by Popovich, et al., would have been considered obvious in view of the conventionality of these enhancements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-272-4977. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez
Primary Examiner
Art Unit 3763

MM